UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 28, 2021

ALTIMMUNE, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-32587**	**20-2726770**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

910 Clopper Road, Suite 201S **Gaithersburg, Maryland** **(Address of principal executive offices)**	**20878** **(Zip Code)**

Registrant's telephone number including area code: (240) 654-1450

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	**ALT**	**The NASDAQ Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On September 28, 2021, Altimmune, Inc. (the "Company") issued a press release announcing positive results from its Phase 1 clinical trial of ALT-801 (pemvidutide) in overweight and obese volunteers.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On September 28, 2021, the Company announced positive results from a 12-week, Phase 1 trial of pemvidutide (proposed INN, formerly known as ALT-801), an investigational glucagon-like peptide-1 (GLP-1)/glucagon dual receptor agonist.

The Phase 1 study was a first-in-human, randomized, placebo-controlled, single ascending dose and multiple ascending dose ("MAD") study in overweight and obese volunteers performed in Australia under a clinical trial application. Eligible participants included healthy, non-diabetic subjects with a minimum body mass index ("BMI") of 25 kg/m2. Thirty-four (34) subjects in the MAD portion of the study were assigned to receive one of three subcutaneous doses of pemvidutide (1.2 mg, 1.8 mg and 2.4 mg) or placebo once weekly for 12 weeks without dose titration. Behavioral and caloric restrictive interventions were not employed.

At 12 weeks, subjects receiving pemvidutide achieved mean weight losses of 4.9%, 10.3%, and 9.0% at the 1.2 mg, 1.8 mg, and 2.4 mg doses, respectively, with the placebo group experiencing a mean weight loss of 1.6%. Weight loss occurred rapidly and consistently over 12-weeks. Side effects were mild to moderate, with no serious or severe treatment-emergent adverse events. Importantly, no discontinuations due to adverse events were reported.

Summary of 12-week MAD weight loss findings

		Treatment			
		1.2mg (n=7)	**1.8mg (n=9)**	**2.4mg (n=11)**	**Pooled Placebo (n=7)**
Baseline demographics					
Age, years	mean	27.7	32.0	31.4	35.3
BMI (kg/m^2)	mean	30.0	30.1	31.8	31.0
Results					
Weight loss (kg)	mean	-4.7	-8.8	-8.4	-1.5
Weight loss (%)	mean	-4.9%	-10.3%**	-9.0%*	-1.6%

* p < .01, **p< .005, compared to placebo

The 1.8 mg dose cohort experienced the highest weight loss, with 100% of subjects losing at least 5% of body weight and 55% of subjects losing at least 10% of their body weight. The amount of weight loss at the 1.8 and 2.4 mg doses were essentially the same given the sample size and overlapping confidence intervals. No correlation was found between the magnitude of weight loss and either age or baseline BMI.

Favorable trends were observed in secondary measures, including reductions in systolic and diastolic blood pressure, serum lipids, and HOMA-IR (a measure of insulin resistance). In addition, a rise in ketone bodies was observed, consistent with the effects of glucagon on fat metabolism.

Summary of 12-week MAD safety findings

Characteristic	Treatment 1.2mg (n=7)	1.8mg (n=9)	2.4mg (n=11)	Pooled Placebo (n=7)
Discontinuations due to adverse events (n)	0	0	0	0
Early withdrawal (n)	1	0	2	2
Nausea				
Mild	14.3%	55.6%	45.5%	14.3%
Moderate	14.3%	11.1%	45.5%	0%
Vomiting				
Mild	14.3%	11.1%	45.5%	14.3%
Moderate	0%	11.1%	27.3%	0%
Diarrhea				
Mild	0%	0%	18.2%	0%
Moderate	0%	0%	0%	0%
Constipation				
Mild	0%	11.1%	18.2%	0%
Moderate	0%	11.1%	9.1%	0%
Other adverse events (n)	0	2	1	0

Even without dose titration, the symptoms experienced by subjects who received pemvidutide 1.8 mg were predominantly mild, did not need treatment and were consistent with known effects of GLP-1 therapies. Further, tolerability decreased with higher dose levels. There were no hyperglycemia adverse events and no increases in the mean heart rate were observed at 6 and 12 weeks of therapy. One patient experienced elevated alanine transaminase levels that resolved rapidly after a pause in dosing.

Pemvidutide development plan

An Investigational New Drug (“IND”) application in non-alcoholic steatohepatitis (“NASH”) has cleared U.S. Food and Drug Administration (“FDA”) review and will enable additional clinical studies beyond the current Phase 1 trial, including a 12-week trial to measure reduction in liver fat content in diabetic and non-diabetic subjects with non-alcoholic fatty liver disease, which is expected to commence in the near future. The Company has commenced a drug-drug interaction trial and also plans to conduct a trial of glucose control in patients with type 2 diabetes that is anticipated to start in the fourth quarter 2021. The Company also intends to begin a 52-week Phase 2 biopsy-driven NASH trial in the first half of 2022.

The Company intends to file a second IND application in obesity in the fourth quarter of 2021 with plans to initiate a 48-week, Phase 2 obesity trial in the first half of 2022.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Altimmune, Inc. dated September 28, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 28, 2021

ALTIMMUNE, INC.

By: /s/ William Brown
Name: William Brown
Title: Chief Financial Officer

Exhibit 99.1

Altimmune Announces Positive Results From 12-week Phase 1 Clinical Trial of ALT-801 (Pemvidutide) in Overweight and Obese Volunteers

- *Mean weight loss of 10.3% achieved in subjects receiving 1.8 mg dose*
- *Pemvidutide was well-tolerated without the need for dose titration*
- *No discontinuations due to treatment-emergent adverse events*
- *NASH IND has cleared FDA review; 12-week NAFLD study to begin in the near future*
- *Altimmune to host a conference call today at 8:30 am EST*

GAITHERSBURG, Md., September 28, 2021 — Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced positive results from a 12-week, Phase 1 trial of pemvidutide (proposed INN, formerly known as ALT-801), an investigational glucagon-like peptide-1 (GLP-1)/glucagon dual receptor agonist.

The Phase 1 study was a first-in-human, randomized, placebo-controlled, single ascending dose (SAD) and multiple ascending dose (MAD) study in overweight and obese volunteers performed in Australia under a clinical trial application. Eligible participants included healthy, non-diabetic subjects with a minimum body mass index (BMI) of 25 kg/m^2. Thirty-four (34) subjects in the MAD portion of the study were assigned to receive one of three subcutaneous doses of pemvidutide (1.2 mg, 1.8 mg and 2.4 mg) or placebo once weekly for 12 weeks without dose titration. Behavioral and caloric restrictive interventions were not employed.

At 12 weeks, subjects receiving pemvidutide achieved mean weight losses of 4.9%, 10.3%, and 9.0% at the 1.2 mg, 1.8 mg, and 2.4 mg doses, respectively, with the placebo group experiencing a mean weight loss of 1.6%. Weight loss occurred rapidly and consistently over 12-weeks. Side effects were mild to moderate, with no serious or severe treatment-emergent adverse events. Importantly, no discontinuations due to adverse events were reported.

“The achievement of double-digit weight loss for subjects in the 1.8 mg arm with predominantly mild side effects reaffirms our enthusiasm for the potential of pemvidutide to be a transformational therapy for obesity and NASH,” said Vipin K. Garg, Ph.D., Chief Executive Officer of Altimmune. “We were able to reach this level of weight loss rapidly without dose titration, which is commonly used with other drugs in the GLP-1 class. With the recent clearance of our NASH IND, we are excited to begin the next phase of development to continue exploring this new therapy and the potential it has to positively impact those with obesity and metabolic disorders.”

“The rapid weight loss and response to pemvidutide across patients and dose groups highlight the therapeutic advantage conferred by balanced agonism at the GLP-1 and glucagon receptors,” said Scott Harris, M.D., Chief Medical Officer of Altimmune. “Given that these weight loss data were obtained without diet or behavioral modifications, we are excited to see weight loss reach its full potential during the planned 48-week Phase 2 obesity trial next year.”

Summary of 12-week MAD weight loss findings

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Baseline demographics					
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Favorable trends were observed in secondary measures, including reductions in systolic and diastolic blood pressure, serum lipids, and HOMA-IR (a measure of insulin resistance). In addition, a rise in ketone bodies was observed, consistent with the effects of glucagon on fat metabolism.

Summary of 12-week MAD safety findings

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Characteristic	1.2mg (n=7)	1.8mg (n=9)	2.4mg (n=11)	Pooled Placebo (n=7)
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Pemvidutide development plan

An Investigational New Drug (IND) application in non-alcoholic steatohepatitis (NASH) has cleared the U.S. Food and Drug Administration (FDA) review and will enable additional clinical studies beyond the current Phase 1 trial, including a 12-week trial to measure reduction in liver fat content in diabetic and non-diabetic subjects with non-alcoholic fatty liver disease (NAFLD), which is expected to commence in the near future. The Company has commenced a drug-drug interaction trial and also plans to conduct a trial of glucose control in patients with type 2 diabetes that is anticipated to start in the fourth quarter of this year. Altimmune also intends to begin a 52-week Phase 2 biopsy-driven NASH trial in H1 2022.

The Company intends to file a second IND application in obesity in Q4 2021 with plans to initiate a 48-week, Phase 2 obesity trial in H1 2022.

About Pemvidutide

Pemvidutide (proposed INN, formerly known as ALT-801) is a novel, investigational, peptide-based dual GLP-1/glucagon receptor agonist that is designed to treat obesity and non-alcoholic steatohepatitis (NASH). Altimmune believes the treatment of obesity is the cornerstone of treating NASH and its co-morbidities and views the treatment of obesity and NASH as significant unmet medical needs that can be addressed through significant weight loss.

Conference Call Information

Altimmune management will host a conference call and webcast with a slide presentation beginning at 8:30 am E.T. Following the conclusion of the call, the webcast will be available for replay on the Investor Relations page of the Company's website at www.altimmune.com. The company has used, and intends to continue to use, the IR portion of its website as a means of disclosing material non-public information and for complying with disclosure obligations under Regulation FD.

Date:	Tuesday, September 28
Time:	8:30 am Eastern Time
Domestic Dial-in:	(844) 615-6509
International Dial-in:	(918) 922-3148
Conference ID:	3792068
Webcast:	https://edge.media-server.com/mmc/p/ojyxaxpp

About Altimmune

Altimmune is a clinical stage biopharmaceutical company focused on developing treatments for obesity and liver diseases. Our pipeline includes next generation peptide therapeutics for obesity, NASH (pemvidutide), and chronic hepatitis B (HepTcell™). For more information, please visit www.altimmune.com.

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Forward-Looking Statement

Any statements made in this press release relating to future financial or business performance, conditions, plans, prospects, trends, or strategies and other financial and business matters, including without limitation, the timing of key milestones for our clinical assets, the initiation of the 12-week NAFLD clinical trial in the near future, the initiation of the Type 2 diabetes trial in Q4 2021, the initiation of a 52-week

NASH clinical trial in H1 2022, the timing of the filing of an additional IND for obesity in Q4 2021, initiation of a 48-week Phase 2 obesity trial in H1 2022, the potential therapeutic effects of ALT-801, the prospects for regulatory approval, our ability to manufacture ALT-801 for our clinical trials and commercial needs, and commercializing or selling any product or drug candidates, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, when or if used in this press release, the words “may,” “could,” “should,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “predict” and similar expressions and their variants, as they relate to Altimmune, Inc. (the “Company”) may identify forward-looking statements. The Company cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time. Important factors that may cause actual results to differ materially from the results discussed in the forward looking statements or historical experience include risks and uncertainties, including risks relating to: potential impacts due to the COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain interruptions, access to clinical sites, enrollment, adverse effects on healthcare systems and disruption of the global economy; the reliability of the results of studies relating to human safety and possible adverse effects resulting from the administration of the Company’s product candidates; the Company’s ability to manufacture clinical trial materials and commercial supply on the timelines anticipated; and the success of future product advancements, including the success of future clinical trials. Further information on the factors and risks that could affect the Company’s business, financial conditions and results of operations are contained in the Company’s filings with the U.S. Securities and Exchange Commission, including under the heading “Risk Factors” in the Company’s annual report on Form 10-K for the fiscal year ended December 31, 2020 filed with the SEC, which is available at www.sec.gov.

Altimmune Investor & Media Contact:

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